

Applicant: Brodeur et al.
Application Serial No.: 09/723,852
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Amendments to the Drawings:

The attached two sheets of drawings include changes to Figure 2 on sheet 1 of 2 and changes to Figure 3 on sheet 2 of 2. These sheets replace the original sheet 1 of 2 including Figure 2 and sheet 2 of 2 including Figure 3.

Attachment: Replacement sheets 1/2 and 2/2.

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REMARKS/ARGUMENTS

Introduction

The Examiner has rejected claims 2-5, 9-13, 15 and 22-25, which represent all the currently pending claims in the application. Claim 22, 24, and 25 have been amended. The Specification has been amended, assigning element numbers 7a and 10a to the "individual strips" of the second body 7 and 10, respectively. Figures 2 and 3 have been amended to show the "individual strips" 7a and 10a, and the replacement sheets are enclosed herewith. Reconsideration of this application as amended is respectfully requested.

Rejections under 35 U.S.C. §112

The Examiner has rejected claims 23 and 25 under 35 U.S.C. §112, first paragraph, as containing subject matter which allegedly was not described in the specification in such as way to enable one skilled in the art to which it pertains to make and/or use the invention.

The Examiner alleged the following:

The structure of the embodiments shown in figures 2 and 3 is unclear. Specifically, it appears that second body 7 (figure 2) and second body 10 (figure 3) extend only partially in the circumferential direction since they are termed "strips" in the specification. Yet, the second bodies (e.g. second bodies 7 and 10) are referred to as tubular bodies throughout the specification. Thus, it is unclear from the disclosure if second bodies 7 and 10 are tubular bodies which extend completely 360 degrees circumferentially or not. In other words, it is unclear if each of the three rectangular blocks on the right side of figure 2 represents a tubular body which extends completely 360 degrees circumferentially or not. If it

does, it is not seen how it can be considered a strip. If it does not, it is unclear where the other strips are which form a tube with the rectangular strip shown.

Applicants respectfully traverse the rejection.

Claim 23 is directed to an implantable composite tubular prosthesis. The prosthesis includes a first plurality of generally straight polytetrafluoroethylene strips, the first strips being arranged to define a first tubular form with the first strips being generally parallel and arranged in non-overlapping relationship to create gaps therebetween; a second plurality of generally straight, separate and independent polytetrafluoroethylene strips the second strips being arranged to define a second tubular form with the second strips being generally parallel and arranged in non-overlapping relationship to create gaps therebetween; and a circumferential deformable support structure interposed between the first tubular form and the second tubular form, wherein the strips of the first tubular form at least partially overlap the gaps of the second tubular form to secure the support structure.

Claim 25 is directed to a method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite. The method includes the steps of positioning a plurality of generally parallel, separate and independent polytetrafluoroethylene strips arranged to define a first tubular form, the strips being arranged in non-overlapping relationship to form gaps therebetween; positioning a deformable support structure over the first tubular form;

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positioning a second plurality of generally parallel, separate and independent polytetrafluoroethylene strips, the second strips being arranged in non-overlapping relationship to define a second tubular form having gaps between the second strips, wherein the second tubular form is positioned at least partially over the gaps of the first tubular form; and securing the second tubular form to the first tubular form to form the prosthesis.

According to MPEP §2164.01, the test of enablement requires a determination of whether the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. Replacement Figure 2 shows the second body 7 as a plurality of separate independent strips 7a arranged in a tubular form. Replacement Figure 3 shows the second body 10 also as a plurality of separate independent strips 10a arranged in a tubular form. Further support is found in the specification which was amended to include element numbers for the individual strips. The specification generally discloses second bodies as:

As shown herein, the second tubular body shown in Figures 1-4 form perimetrically non-continuous bodies from PTFE components tubularly assembled (page 7, line 19-20).

More specifically, the specification disclosed second bodies 7 and 10 including individual strips 7a and 10a as:

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As seen in Figures 2 and 3, the second body 7 and 10 may be individual strips 7a and 10a which may be non-continuous having longitudinally arranged segments (page 8, line 2-4).

The specification further defines non-continuous as "a tubular structure which is not substantially uninterrupted along its length"(page 7, line 21-22). Therefore, specification and drawings, as taken in its entirety, discloses the second bodies 7 and 10 as a plurality of generally straight, separate and independent strips being arranged to define a tubular form with the strips being generally parallel and arranged in non-overlapping relationship to create gaps therebetween as set forth in claims 23 and 25.

Claim 23 and 25 are, in fact, sufficiently described in the specification and, thus, are fully enabled. The second body is tubular and collectively formed of a plurality of strips, as would be understood by one skilled in the art.

It appears that the Examiner is finding an inherent tension between the use of the term "strips" and the tubular structure of the second body. This notion by the Examiner presupposes that the strips cannot be ring-shaped (i.e., traverse 360°). As would be recognized by one skilled in the art from the Applicants' specification, the strips can be ring-shaped or have a radial length less than 360°.

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Further, the Examiner acknowledged that the Figures and specification contained enough information to enable second bodies 7, 10 as both extending only partially in the circumferential direction and 360 degrees. However, it appears that the Examiner has labeled the term "strips" to mean extending only partially in the circumferential direction, and the term "tubular bodies" to mean extend circumferentially 360 degrees. The Examiner appears to require the Applicants to choose between the terms to limit the definition of "second bodies" and in turn narrow the scope of the application and the claims, accordingly. However, Applicants are not required to limit the scope of an element, the claims and the specification narrower than what was originally filed, in accordance with 35 U.S.C. § 112, first paragraph.

Generally, a "strip" is defined as "a long narrow piece of a material", *Merriam-Webster Online Dictionary*. A "long narrow piece of material" may be used to form a variety of shapes. Claim 23 and 25 arrange individual long narrow pieces of material (strips) 7a and 10a in the circumferential direction about the support structure 6 and 9, as shown in Figures 2 and 3. Further, the strips 7a and 10a may be oriented as a ring shape, being 360 degrees circumferentially, or less than 360 degrees circumferentially. Both configurations are strips being long narrow pieces of a material, in accordance with the *Webster Dictionary* definition. Further, the individual strips 7a and 10a can be collectively placed longitudinally along the support structure to form a tubular body 7 or 10, as shown in Figure 2 and 3.

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Applicants believe that the claims 23 and 25 as currently standing comply with the requirements of 35 U.S.C. §112. The rejection is therefore respectfully traversed.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Rejections under 35 U.S.C. §103

The Examiner has rejected claims 2-5, 9-13, 15, 22 and 24 under 35 U.S.C. §103(a) as allegedly being unpatentable over European Patent No. 0893108 to Ray. The Examiner stated:

The reference to "Longitudinally extending strip" in col. 9, lines 18-21 of Ray clearly refers to strips that extend along (parallel to) the longitudinal axis of the prosthesis since such strips are "Longitudinally extending". Further, the use of this phrase rather than the term "helical" (which is used to describe other embodiments) indicates that a structure other than helical is intended. It would have been obvious that these strips are non-overlapping since the windings of the strip 8 shown in the figures are non-overlapping. The reference to stress relief zones (e.g. col. 4, lines 4-13) refers only to one embodiment ("a preferred embodiment" as described in col. 4, line 4) wherein the coupling member is arranged in a helical configuration rather than the configuration of longitudinally extending strips described in col. 9, lines 18-21.

Amended claim 22 is directed to an implantable composite tubular prosthesis. The prosthesis includes a first polytetrafluoroethylene tubular body; a plurality of generally straight separate and independent polytetrafluoroethylene yarn-shaped strips, the strips being arranged to define a tubular form with the strips being generally parallel and arranged in non-overlapping

relationship; and a circumferential deformable support structure interposed between the first tubular body and the tubular form, wherein the strips being secured to the first tubular body.

Additionally, amended claim 24 is directed to a method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite. The method includes the steps of providing a first polytetrafluoroethylene tubular body; positioning a deformable support structure over the first tubular body; positioning a plurality of generally parallel, separate and independent polytetrafluoroethylene yarn-shaped strips arranged in non-overlapping relationship over the support structure to form a tubular form; and securing the strips to the first tubular body.

Claim 22 and claim 24 have been amended to define the PTFE strips of the tubular form as being yarn shaped. Support of this amendment is found in the specification on page 10, line 13-14. However, Ray teaches a coupling member being formed from a generally flat ribbon or tape. Ray teaches the coupling member has a broad or flat surface to increase bonding surface area between the coupling member and the graft member, which enhances the structural integrity of the stent-graft (col.7, line 38-52). Further, Ray teaches away from a yarn like structure as recited in the amended claims 22 and 24 (col.7, line 38-41). The yarn-like surface fails to

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provide the broad and flat surface area for interfacing with the stent and graft member as taught by Ray.

Ray fails to teach or suggest the yarn-shaped structure of the presently claimed invention. As claims 2-5, 9-13, and 15 depend from amended claim 22, the above-argument equally applies thereto. Therefore, Applicants respectfully request withdrawal of the rejection and request reconsideration of independent amended claims 22 and 24, and dependent claims 2-5, 9-13 and 15.

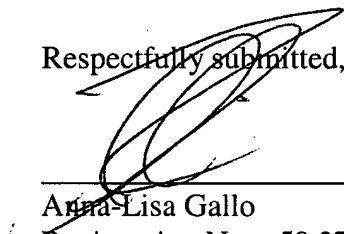
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SUMMARY

Applicant respectfully submits that claims 2-5, 9-13, 15, 23 and amended claims 22, 24 and 25 are patentably distinct, and enabled by the specification. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning this application or this amendment, he is invited to contact the undersigned counsel.

Respectfully submitted,



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